

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

CRIMINAL NO.

VIOLATION:

V.

18 U.S.C. §371

Conspiracy to Violate Title 21 U.S.C.

Sections 331(t) and 333(b)

TAP PHARMACEUTICAL
PRODUCTS INC.

Defendant

INFORMATION

The United States Attorney charges that:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendant

TAP PHARMACEUTICAL PRODUCTS INC.

1. TAP Pharmaceutical Products Inc., hereinafter "TAP", is a Delaware corporation with its principal place of business in Lake Forest, Illinois. TAP's shares are not publicly traded; TAP's shares are equally owned by Abbott Laboratories, an American corporation with a principal place of business in Abbott Park, Illinois, and Takeda Chemical Industries, Ltd., a Japanese corporation with a principal place of business in Osaka, Japan. At various times during

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the 1990s, TAP was known as "TAP Pharmaceuticals Inc." and "TAP Holdings Inc."

2. From in or about 1989 through the date of this Information, TAP sold a drug called Lupron in several different formulations. Like any drug, distribution of Lupron for human use was subject to the requirements of the Federal Food, Drug and Cosmetic Act. At all times material hereto, TAP had approval to distribute Lupron in a number of different formulations for a specific list of approved uses, including for the treatment of prostate cancer in men suffering from that disease. In the marketing of Lupron, TAP employed and maintained extensive marketing and sales departments. Since at least the early 1990s, TAP has sold and provided the drug Lupron Depot to urologists across the country, including to urologists practicing medicine in the Commonwealth of Massachusetts, and to, among other physicians, Dr. Joseph Spinella, practicing in the State of Connecticut, Dr. Joel Olstein, practicing in the State of Maine, Dr. Jacob Zamstein, practicing in the State of Connecticut, and Dr. Rodney Mannion, practicing in the State of Indiana.

3. Lupron Depot was administered to patients by intramuscular injection, typically in the buttocks, by a physician or nurse under the supervision of a physician. At various times in the 1980s and continuing to the present, Lupron was available in daily, one month, three month and four month doses. When Lupron was initially introduced to the marketplace, it was in the form of daily injections that were self injected. Over time, the monthly, three-month, and four-month doses of Lupron Depot were approved for use and typically, patients would not self-administer these dosage levels. It was typical that a patient whose prostate cancer was being treated with Lupron Depot would receive regular injections of that drug for the remainder of his life. At times material to this Information, the majority of patients receiving regular doses of

Lupron Depot were administered the one month, three month and/or four month doses.

4. At all times material to this Information, TAP sold Lupron Depot to physicians and to health maintenance organizations, among other purchasers. At all times material to this Information, an industry reference known as the Red Book published a price, called the Average Wholesale Price or AWP, for Lupron Depot based upon information supplied to the Red Book's publishers by TAP. At all times material to this Information, the AWP for an injection of a monthly dose of Lupron Depot administered to a patient was as follows:

	Average Wholesale Price
1992	418.75-437.50
1993	451.25
1994	463.75
1995	477.50
1996	496.25-515.63
1997	540.63
1998	566.88

5. At all times material to this Information, it was a crime, in violation of Title 21, United States Code, Sections 331(t) and 333(b) for an employee of a company engaged in the lawful distribution of drugs to provide a drug sample free of charge to a physician, with the intention and expectation that the physician would use that sample in the treatment of a patient and thereafter seek and receive reimbursement for that drug sample which had been provided to the physician free of charge.

6. Beginning in or about 1991 and continuing to in or about 1998, the defendant TAP,

through its employees, provided to certain physicians thousands of free samples of the drug Lupron, knowing and expecting that those physicians would prescribe and administer those drug samples to their patients and thereafter seek and receive reimbursement for those free samples.

COUNT 1: 18 U.S.C. §371 (CONSPIRACY)

7. Paragraphs 1 through 6 of this Information are herein realleged and incorporated by reference.

8. From in or about 1993 through in or about 1998, in the District of Massachusetts, and elsewhere throughout the United States, the defendant

TAP PHARMACEUTICAL PRODUCTS INC.

together with certain of its employees, certain urologists practicing medicine in Massachusetts and elsewhere, and together with others known and unknown to the United States Attorney, did knowingly and willfully combine, conspire and agree to violate Title 21 U.S.C. Sections 331(t) and 333(b) by submitting, and by causing to be submitted, claims for payment for Lupron Depot which had been provided as free samples to the urologists.

OBJECTIVE OF THE CONSPIRACY

9. The objectives of the conspiracy varied depending upon the participant. The core objective of this conspiracy for all participants was to obtain money from the reimbursement for samples of Lupron. It was an objective of TAP in this conspiracy to provide free samples of Lupron Depot, as well as other things of value, including money, to certain physicians as an inducement to those physicians to order Lupron Depot. It was also an objective of this conspiracy for TAP to give free samples to physicians who had not timely paid TAP for balances due on past purchases of Lupron, in order to provide the physician with a source of money from which the physician could generate funds to pay that past-due balance. It was an objective of some of the physicians participating in this conspiracy to bill for the free samples in order to increase their income.

OVERT ACTS

10. In furtherance of the conspiracy, the defendant TAP and other conspirators known and unknown to the United States Attorney committed among other acts the following overt acts in the District of Massachusetts and elsewhere:

a. On various dates beginning in 1993 and continuing into at least July, 1996, employees of TAP provided to Dr. Rodney Mannion for free more than sixty-one samples of Lupron Depot.

b. On various dates in beginning in 1993 and continuing through at least July 1996, Dr. Mannion sought and received reimbursement for samples of Lupron Depot which he had received for free from TAP.

c. On various dates beginning in 1993 and continuing into at least July, 1996, employees of TAP provided to Dr. Jacob Zamstein for free more than eighty samples of Lupron Depot.

d. On various dates beginning in 1993 through continuing through at least July 1996, Dr. Zamstein sought and received reimbursement for samples of Lupron Depot which he had received for free from TAP.

e. On various dates beginning in 1993 and continuing into at least July, 1996, employees of TAP provided to Dr. Joseph Spinella for free more than fifty samples of Lupron Depot.

f. On various dates in 1993 through at least July 1996, Dr. Spinella sought and received reimbursement for samples of Lupron Depot which he had received for free from TAP.

g. On various dates beginning in 1993 and continuing into at least July, 1996, employees of TAP provided to Dr. Joel Olstein for free more than sixty-one samples of Lupron Depot.

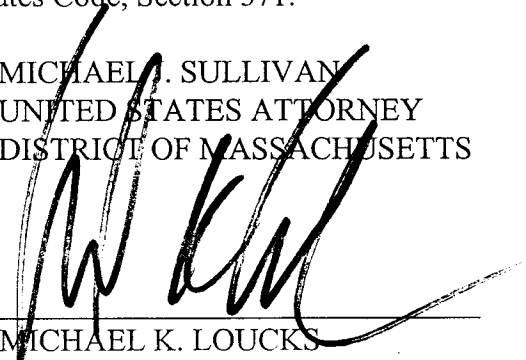
h. On various dates in 1993 through at least July 1996, Dr. Olstein sought and received reimbursement for samples of Lupron Depot which he had received for free from TAP.

i. On various dates in the time period 1994 through at least 1996, employees of TAP provided one-month samples of Lupron Depot, without charging therefor, to certain physicians in the District of Massachusetts, with, among other intents, the intention and expectation that the physician receiving the free samples of drug would use those samples in the treatment of a patient suffering from prostate cancer and thereafter seek and receive reimbursement for that drug.

All in violation of Title 18, United States Code, Section 371.

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By:



MICHAEL K. LOUCKS
HEALTH CARE FRAUD CHIEF and
ASSISTANT U.S. ATTORNEY

October 3, 2001